APR 3 0 2001

K010365
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510(k) Summary

Company Name
Personal Products Company Division of McNeil-PPC, Inc.
199 Grandview Road Skillman, NJ. 08558

Device Name
Proprietary Name: Ortho® Control Female Urinary Control Device
Common Name: External Female Urinary Incontinence Device

Description
The Ortho® Control Female Urinary Control Device, (OCFUCD) is a non-sterile, daily wear, soft silicone device of single unit construction, consisting of a flexible cylinder (cap) surrounded by a soft pliable flange (base). The device is designed to be worn directly over the external female urethral meatus, between the labia, posterior to the clitoris, and anterior to the vagina. It is held in place by a mild vacuum pressure exerted by the device plus the folds of the external female labia. The vacuum is created when the cylindrical portion (cap) of the device is squeezed to express air. The resulting negative pressure occludes the meatus preventing accidental leakage while increasing the resistance in the distal urethra, helping to support and reinforce the natural action of the muscles that control urinary output. This device is worn external to the body. It is not a tampon, absorbent, collection cup or reservoir. A small amount of "application gel" (USP white petrolatum) is applied to the device flange or base, prior to placement. The petrolatum helps to create a watertight seal and prevent slippage. The device is removed for normal urination and then reapplied after voiding.

Intended Use
The Ortho® Control Female Urinary Control Device is intended to minimize urinary leakage in women caused by sneezing, coughing, laughing, and moderate physical activity. (Stress incontinence)

A user may choose to wear the device on a daily basis or only during periods of excessive physical activities when it is anticipated that the risk of urinary leakage will be greater, e.g. dancing, jogging or playing tennis etc.. The device is discarded at the end of the day.

Rationale
At least 13 million Americans suffer from urinary incontinence of those, 11 million are adult women. Stress incontinence is the primary form of the condition, affecting 65% of sufferers, especially women who have gone through vaginal childbirth. Incontinence can effect quality of life from a physical, emotional, social, and medical standpoint, significantly impeding lifestyle choices. It has been reported that women sufferers may limit physical activities, restrict travel according to restroom access, or avoid leaving the house altogether. They may also restrict social interactions, have reduced sexual drive, loss of self-esteem or even suffer depression. Because of the

social stigma attached to incontinence, women are reluctant or too embarrassed to discuss the problem with their physicians and therefore have no recourse other than existing over-the-counter treatments limited to absorbent products.

As a result, many incontinent sufferers have relied strictly on absorbent products such as sanitary pads, adult diapers and tampons to treat this problem. Since absorbents merely trap urine leakage, other problems can occur from this usage such as odor, chafing, rashes, irritations, and skin infections. Incontinence suffers spend thousands of dollars annually on additional products such as deodorants, disinfectants and skin care products to help manage these and other consequences associated with urinary incontinence.

The Ortho® Control Female Urinary Control Device offers stress incontinent women an alternative to the currently limited over-the-counter choices. It is a safe, non-surgical, non-chemical, non-invasive, option for women to be available without a prescription.

Clinical Testing has demonstrated that the device not only minimizes leakage but in many cases, stops leakage before it occurs. Secondary benefits may include, improvement to quality of life as well as prevention of odor, chafing and irritation associated with urinary wetness.

Predicate Devices

Two predicate prescription versions (FemAssist™ Personal Urinary Control Device) sponsored by Insight Medical of Bolton, MA, were 510(k) cleared as non-significant risk devices via K963858 and K974645 respectively. Additionally, another urethral occlusive patch device, Soft Patch™ sponsored by Advanced Surgical Intervention, (subsequently UroMed® Corporation, Needham MA) [predicate device Miniguard (Impress Patch™)], received 510(k) clearance initially as a prescription device (K954215) followed by FDA clearance for an over-the-counter indication (K974600). The Soft Patch™ product is currently not available.

Substantial Equivalence

Substantial equivalence was demonstrated by comparing the Ortho® Control Female Urinary Control Device (OCFUCD) to its predecessor, FemAssist™ Personal Urinary Control Device (FAPCUCD) in several laboratory tests and clinical studies.

Laboratory Testing

- **Vacuum Pressure** created by the Ortho Control Female Urinary Control Device (OCFUCD) was compared to the FemAssist™ Personal Urinary Control Device (FAPUCD) and demonstrated to fall within the range established by the FAPUCD.

- **Leak Pressure**, required to create a leak in the OCFUCD was compared to FAPUCD and found to be statistically equivalent.

- **Pull-Off Forces** measured in lbf, compared the force required to remove the OCFUCD from a control surface to that of the FAPUCD demonstrated an increase in pull off force with OCFUCD rendering it unlike to dislodge during use.
- **Tensile Fracture** ratio of tensile fracture point to the pull-off force represents a tear resistant safety factor, demonstrating that the OCFUCD has a 3 fold greater tear resistance than FAPUCD.

For Pull-Off Forces and Tensile Fracture, the Ortho Control Device was statistically better when compared to the FemAssist™ device.

Clinical Safety and Efficacy

Predicate Device

The safety and effectiveness of the predicate, FemAssist™ Personal Urinary Control Device, in stress incontinent females, was cleared by FDA via K963858. Clinical studies were conducted at two different geographical locations in the U.S.
A standardized one-hour pad weighing test designed to measure urine leakage before and after use was utilized to assess efficacy. After qualifying for inclusion at the study site, participants used the device at home for up to 28 days and returned to the study site doctor for repeat one-hour pad weighing tests. Of those participating; 76% achieved at least 50% or greater reduction in urine loss. 32.9 % were 100% dry (no leakage), 30.1% achieved a 75-100% reduction, 13.7% achieved a 50-75% reduction 8.2% achieved 0-50% reduction and 15%.1% reported an increase in urine loss. Adverse experiences were obtained from voiding diaries and physician visits. Thirty-five percent of which were for discomfort, 10% urinary tract infection, 6% urethral irritation, 5% bleeding, 3% discharge and 1% yeast infection.

This pivotal study was published by the lead investigator, Eboo Versi, MD, Ph.D et. al, *A New External Urethral Occlusive Device for Female Urinary Incontinence* Obstet Gynecol 1998-92:286-91. Scores on visual analogue scales improved for symptoms of stress incontinence, urgency and urge incontinence ($P < .001$). Scores for increased irritation discomfort increased only ($P < .0001$). Pad weighing tests both at one hour and 48 hours yielded a p value of $< .001$. Quality of life scores were significantly improved in 48%.

Application/Safety Study

An Application/Safety Study with the Ortho Control Female Urinary Control Device demonstrated the safety, ease of application and wearability of the device as reported in a Combined Clinical/Statistical report by this sponsor. This study evaluated pre and post-menopausal women with and without a history of mild to moderate stress urinary incontinence. Safety assessments included urinalyses and peri-urethral examinations. No serious adverse events were documented. Those adverse events that did occur did not jeopardize the health of the subjects. Most were genitourinary episodes of periurethral irritation or excoriation which resolved upon removal.

Size Selection Study
A Size Selection Study with the Ortho Control Female Urinary Control Device was conducted by this sponsor at a prominent teaching Hospital in New Brunswick, NJ. This study was to understand the proper size requirements and to determine the comfort of two different sizes of the device (petite and medium) in peri and post menopausal women. The two sizes were tested in both a standard and flexible rigidity version. An examination of the peri-urethral area for any abnormalities, age, menopausal status and histories of vaginal delivery were recorded at entry. Women were asked to place the device according to the instructions provided. Clinical personnel observed this placement and checked the device for proper fit. All subjects completed two hours of light activity followed by completion of a questionnaire concerning ease of placement, movement of the device, comfort and messiness of the application gel. After removal of the device, 92% had normal peri-urethral examination results and 0.08% had abnormal results. The abnormal results or adverse experiences were reported as mild peri-urethral erythema and irritation probably associated with the device and not requiring treatment. All adverse experiences resolved upon discontinuation.

Consumer Concept/Use Study
A Market Research study sponsored by Personal Products Company was conducted to obtain quantitative consumer feedback regarding opinions and attitudes and reactions towards the Ortho Control Female Urinary Control Device. The device was tested using two different versions Standard and Flexi in two different sizes (petite and medium). After reviewing the concept and answering questions, participants were randomly assigned to the order of usage of the two types of devices for a 1 week home use trial. If still positive after the home trial, these participants were given a second version for a week 2 trial. Upon completion of the home trial, participants answered a questionnaire. A total of 16% of subjects reported one or more adverse events during the study. The most frequently occurring adverse events were in the urinary system and considered mild to moderate. No serious adverse events were reported during the study. Overall the subjects felt that the device either met or exceeded expectations because it was effective and more comfortable than perceived. In this study, the Petite Standard version emerged as the most preferred among the products tested and therefore was chosen for market launch.

Consumer Label Comprehension
A Label Comprehension Study was conducted to determine levels of comprehension of the package label and instructions for use. The labeling developed from the prescription product, was modified to provide easy to use placement instructions, appropriate product usage and to clearly communicate warnings and self-selection criteria at the point of purchase. Virtually all participants were able to understand what the purpose of the product. Nine out of 10 recognized inappropriate use situations. Areas of confusion identified in the study, were addressed by the addition of a Question and Answer section and some minor revisions to the package insert.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 3 0 2001

Ms. Marylou Panico
Manager Regulatory Affairs, Women's Health
Personal Products Company
Division of McNeil-PPC, Inc.
199 Grandview Road
SKILLMAN NJ 08558

Re: K010365
Ortho Control™ Female Urinary Control Device
Dated: February 6, 2001
Received: February 7, 2001
Unclassified/Procode: 78 MNG

Dear Ms. Panico:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) INDICATIONS FOR USE FORM
(Replica of FDA Form)

510(k) Number (if known): K010365

Device Name: Ortho® Control Female Urinary Control Device

Indications For Use:

To minimize urinary leakage in women caused by sneezing, laughing and moderate physical activity (Stress Incontinence).

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-the-Counter-Use ✓
(per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K010365